IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DEBRA WISE, et al.,

Plaintiffs,

v. **CIVIL ACTION NO. 2:12-cv-01378**

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Dr. Austin *Daubert* Motion)

Pending before the court is the plaintiffs' Motion to Exclude the Opinions and Testimony of Marshall Austin, M.D., Ph.D. [Docket 203]. For the reasons set forth below, the Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 10,000 of which are in the Bard MDL, MDL 2187. In this particular case, the plaintiff, Debra Wise, was surgically implanted with the Avaulta Plus Anterior Support System and the Avaulta Plus Posterior Support System (collectively "Avaulta"), mesh products manufactured by Bard to treat POP. (*See* Short Form Compl. [Docket 1], at 2).[1] The plaintiff received her surgery in West Virginia. (*Id.* at 4). The plaintiff claims that

[1] The present case is part of Wave 1 of the Bard MDL, MDL 2187. (Pretrial Order # 118 (Docket Control Order for Selection and Discovery of 200 Cases) [Docket 15]). Because the parties agree that the Southern District of West Virginia is the proper venue, I set this case for trial in the Southern District. (*See* Am. Joint Submission, MDL 2187 [Docket 1004], at 8; *see also* Order [Docket 63]).

as a result of implantation of the Avaulta products, she has experienced multiple complications, including vaginal spasms, damage to her ureter, vagina, and rectum, kidney reflux, urinary tract infections, chronic constipation, dyspareunia (pain during sexual intercourse), lower pelvic pain, incontinence, and kidney stones. (*See* Pl. Fact Sheet [Docket 102-9], at 7). The plaintiff alleges negligence, strict liability for design defect, strict liability for manufacturing defect, strict liability for failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (Short Form Compl. [Docket 1], at 4).[2] Additionally, the plaintiff's husband, Ronald Wise, alleges loss of consortium. (*Id.*). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the plaintiffs' efforts to exclude or limit the experts' opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must,

[2] By Memorandum Opinion and Order entered on February 5, 2015, I granted Bard's Motion for Summary Judgment with respect to the plaintiffs' claims of strict liability for manufacturing defect and breach of warranty. (*See* Mem. Op. & Order (Def.'s Mot. for Summ. J.) [Docket 224]).

however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[3] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the

[3] With more than 70,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

With these principles in mind, I now turn to the plaintiffs' Motion.

III. Discussion

Dr. Marshall Austin is a pathologist who specializes in gynecologic surgical pathology and cytopathology. He has practiced in this field for almost thirty years. During this time, he has published over 130 peer-reviewed pathology research articles, and he has reviewed approximately 300 to 400 tissue specimens per month, most of which originate from gynecological or breast tissue. (Austin Report [Docket 203-1], at 2). In addition, about 15–20 of the specimens he evaluates each month involve medical devices, such as pelvic mesh, intrauterine devices, sutures, and abdominal hernia mesh. (*Id.* at 2–3). Bard offers Dr. Austin as an expert witness on the biocompatibility of polypropylene, the import of the Material Safety

Data Sheet ("MSDS") for polypropylene resin, and the general pathology of explanted tissue. The plaintiffs challenge several of these opinions, and I address each in turn.

1. Opinions on Product Design and Polypropylene

First, the plaintiffs argue that Dr. Austin lacks the qualifications necessary to render opinions about the biocompatibility of polypropylene, set forth in Section III of his expert report. They point to his deposition, wherein he admitted that he has never designed a medical device and "is not an expert on polypropylene." (Pls.' Mot. to Exclude Ops. & Test. of Dr. Austin & Br. In Supp. ("Mot.") [Docket 203], at 2–3). I do not find this testimony as dispositive in light of Dr. Austin's demonstrated knowledge, training, and experience as a gynecological surgical pathologist. *See, e.g.*, Coll. of Am. Pathologists, *CAP Fact Sheet*, http://www.cap.org (last visited Feb. 9, 2015) ("[Clinical pathologists] are involved in a broad range of disciplines, including surgical pathology, cytopathology, dermatopathology, . . . clinical chemistry, microbiology, immunopathology, and hematology."). In addition to his extensive background in the field of gynecological pathology, where his experience ranges from publishing research to giving academic lectures, Dr. Austin has examined hundreds of vaginal mesh explants over the past ten years. (*See generally* Austin Report [Docket 203-1]). I find his qualifications sufficient to testify about the biocompatibility of mesh. *See, e.g.*, *Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–20 (S.D. W. Va. Sept. 29, 2014) (finding Dr. Trepeta's background and training as a clinical pathologist, in addition to his experience with examining mesh explants, as sufficient to qualify him to testify about "the chemistry and surgical pathology of materials like transvaginal mesh"). The shortcomings emphasized by the plaintiffs in an attempt to deride Dr. Austin's expertise—such as his failure to differentiate between polypropylene and polyester—are better suited for cross-examination.

The plaintiffs also contend that Dr. Austin's opinions on polypropylene's biocompatibility do not have a reliable basis as required by *Daubert* because he does not cite peer-reviewed literature in reaching his opinion and relies only on his experience as a pathologist. I disagree. Dr. Austin's expert report and the accompanying attachments indicate that he relied on dozens of studies and articles in reaching his opinions. Furthermore, Dr. Austin applied the methodology that pathologists generally use when reviewing pathology slides and determining clinical correlations. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . . ."). He reviewed pathological slides, compared his observations to published medical literature, and provided diagnostic interpretations of what he saw. (*See* Austin Dep. [Docket 240-3], at 378:7–384:3 (describing the process of examining pathology slides and reaching diagnostic conclusions)). For these reasons, I **FIND** Dr. Austin's opinion on the biocompatibility of polypropylene as proper for the purposes of *Daubert*, and the plaintiffs' Motion with respect to this opinion is **DENIED**.

The plaintiffs also object to the opinions set forth in Section II of Dr. Austin's report regarding "product design generally, or the Avaulta [products] specifically." (Pls.' Reply in Supp. of Their Mot. to Exclude Ops. & Test. of Dr. Austin [Docket 243], at 2). In Section II, Dr. Austin describes the Avaulta products, and he refers to the position statement of the American Urogynecologic Society, which supports the use of mesh in products used to treat POP or SUI. (*See* Austin Report [Docket 203-1], at 3–4). Then, later in his report, he concludes that Bard's products "do not have inherent design defects." (*Id.* at 38). I agree with the plaintiffs that these opinions about the Avaulta's overall design go beyond Dr. Austin's expertise. While he has studied and observed the interaction between tissue and mesh products such that he can opine about biocompatibility, he has no demonstrated experience in designing or evaluating

transvaginal products. Moreover, stating that the Avaulta has no "inherent design defects" constitutes a legal conclusion that this court will not accept at trial. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

Dr. Austin satisfies the rigors of *Daubert* with respect to his opinions about the biocompatibility of polypropylene, but he lacks the expertise required to extrapolate further. Thus, his opinions on whether or not the Avaulta product has a defective design are **EXCLUDED**. The plaintiff's Motion with respect to this opinion is **GRANTED**.

2. Opinions Regarding Pore Size

Next, the plaintiffs challenge Section V of Dr. Austin's report, wherein he opines that the measured pore size in the Avaulta Plus "was reasonable as it is in line with approaches used in the literature," and "any subsequent reduction in pore size would be irrelevant as the tissue ingrowth would have already occurred." (Austin Report [Docket 203-1], at 7–8). The plaintiffs assert that Dr. Austin is not qualified to offer these opinions because he admitted that he "[is] not an expert in pore size." (Austin Dep. [Docket 240-3], at 150:9). Dr. Austin, however, does not purport to be an expert in pore size, nor is expertise in pore size necessary for him to provide the opinions set forth in his expert report. Rather, Dr. Austin limits his opinions to an explanation of how tissue responds to the pore size of mesh. (*See* Austin Report [Docket 203-1], at 6 ("[P]ore sizes ranging above 1,000 microns, like the Bard products, are more than sufficient to permit tissue ingrowth with normal wound healing and foreign body reactions."); *id.* at 10 ("[T]he pore size of the Bard products was adequate for sufficient tissue growth.")). As explained above, Dr. Austin's background and experience in the field of gynecological pathology provide the requisite expertise needed to testify about the reaction between mesh and tissue. He has observed vaginal

tissue ingrowth through various mesh products, and he has reviewed numerous publications and studies on how pore size can affect the integration of polypropylene with the surrounding tissue. (*See* Austin Report [Docket 203-1], at 2–3 ("Throughout my pathology career, I have encountered implanted medical devices in routine specimens submitted for pathologic evaluation, including, for example, pelvic mesh, ..."); *id.* at 6 n.6 (listing the relied-upon literature)). Accordingly, I **FIND** that he is qualified to testify about the ways in which pore size can affect the biocompatibility of polypropylene. Bard's motion regarding Dr. Austin's testimony on pore size is **DENIED**.

In Section V of his report, Dr. Austin also opines about the animal study Bard conducted to determine the appropriate pore size for effective wound healing. The plaintiffs object to this opinion on the basis that during deposition, Dr. Austin agreed that he had no opinions on the appropriateness of the study and would limit his testimony to "say[ing] they did some studies to look at the issue." (Austin Dep. [Docket 240-3], at 170: 15–16).[4] The statement that Bard "did some studies" does not convey an expert opinion that the court can review under *Daubert*, and therefore, I decline to address the admissibility of this non-expert testimony here.

3. Opinions About Mesh/Tissue Contraction

Again attacking Dr. Austin's qualifications, the plaintiffs assert that the court should not allow Dr. Austin to offer opinions on wound healing, the foreign body response, and the contraction of tissue around a foreign body. The plaintiffs point to extracted statements from his deposition in support of their argument, where Dr. Austin testified that he is not an expert on the "contraction of meshes." (Mot. [Docket 203], at 10 (quoting Austin Dep. [Docket 203-1], at 169:14–21)). This single statement from hundreds of pages of deposition does not overcome Dr.

[4] Because Bard does not respond to the plaintiffs' objection to this opinion, I assume that Dr. Austin's opinion will indeed be limited as indicated by his deposition testimony.

Austin's undeniable expertise as a pathologist. His training and experience in this field equips him to examine tissue and to opine about the tissue's pathology, including its reactions with other present substances, such as mesh. *See, e.g.*, 33 Am. Jur. *Trials* 467, § 17 (1986) ("Clinical pathology is the area of pathology that deals with testing of various body fluids and excreta in an attempt to correlate changes found in those fluids with the presence and development of disease processes."); *id.* § 27 ("Upon receipt of the specimen it is necessary to begin a series of steps that will eventually allow the [] pathologist to establish or confirm a diagnosis based on the specific pathology of the tissue."); (*see also* Austin Dep. [Docket 240-3], at 195:12 ("My focus is on the tissue reaction in the slide.")). Therefore, I **FIND** Dr. Austin qualified to opine on the pathology of mesh explants, which includes an analysis of the foreign body response and how a wound heals around mesh. Any "self-contradiction" or inconsistencies in these opinions can be challenged during cross-examination. *See McReynolds v. Sodexho Marriott Servs., Inc.*, 349 F. Supp. 2d 30, 40 (D.D.C. 2004) (stating that the inconsistencies or misstatements in an expert's testimony "go to credibility, rather than *Daubert*'s standard of admissibility"). Accordingly, I **DENY** Bard's motion on this matter.

4. Opinions Regarding the MSDS

The plaintiffs' objections to Dr. Austin's opinions on the MSDS are **DENIED as moot**, given that Bard has agreed that Dr. Austin will not offer any testimony on the MSDS or why it was drafted. (*See* Def.'s Mem. of Law in Opp. to Pls.' Mot. to Exclude the Ops. & Test. of Dr. Austin [Docket 240], at 11).

5. Opinions Regarding the Motivations or Credibility of Plaintiffs' Experts

Finally, the plaintiffs object to Dr. Austin's rebuttal of the opinions of plaintiffs' expert, Dr. Klosterhalfen. Specifically, the plaintiffs oppose Dr. Austin's opinion on the credibility and

bias of Dr. Klosterhalfen's research. (*See* Austin Report [Docket 203-1], at 9 (implying that because Dr. Klosterhalfen receives royalties on the sales of a mesh product he designed, he has a conflict of interest that discredits his work)). In the plaintiffs' view, an opinion on the purported bias of an author goes to the author's state of mind and is therefore improper expert testimony. I disagree. Dr. Austin's critique of Dr. Klosterhalfen's work does not go to Dr. Klosterhalfen's state of mind but instead explains the reasons why Dr. Austin accepted some studies while rejecting others. (*See id.* at 9 (stating that Dr. Austin was "skeptical" of Dr. Klosterhalfen's research when developing his opinions in this case)). Put differently, this section of Dr. Austin's report concerns Dr. Austin's methodology, not Dr. Klosterhalfen's state of mind. *See Daubert*, 509 U.S. at 595 (stating that the court should "focus [] on principles and methodology, not on the conclusions they generate"). Therefore, I reject the plaintiffs' argument and **DENY** their motion on this matter.

IV. Conclusion

As explained above, the plaintiffs' Motion to Exclude Opinions and Testimony of Marshall Austin, M.D., Ph.D. [Docket 203], is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 11, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE